Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2060779	(X3) Date Survey Completed 12/16/2021
Name of Provider or Supplier Mrh Medical Group-East Main Family Medical	**Street Address, City, State** 1424 E Main St, Tupelo, MS	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Boule Medonic M Series hematology analyzer maintenance records from January 2020 until survey on 12/16/21 and interview with the laboratory technical consultant/laboratory director (TC/LD) at 1:00 p.m. on 12/16/21, the laboratory failed to document as performed the monthly and semi-annual maintenance as required by the manufacturer. Findings include: A. Review of the Medonic M Series manual revealed that the following maintenance is required by the manufacturer: 1. Monthly - Monthly Cleaning (Hypochlorite), Clot Prevention (Enzymatic) 2. Six Month - Boule Cleaning Kit Procedure B. Review of the monthly maintenance records from January 2020 until December 2021 indicated that the monthly maintenance had ONLY been documented as performed in February, March, April, June, July, and October of 2020 and January and December of 2021. C. Review of the six month maintenance records indicated that it had not been documented as performed since January of 2020. D. Interview with the TC/LD at 1:00 p.m. on 12/16 /21 confirmed maintenance was not documented as performed on the Boule Medonic M Series as required by the manufacturer.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Medonic M Series hematology calibration records from last survey 9/12/19 through 12/16/21 and interview with the technical consultant /laboratory director (TC/LD) at 12:30 p.m. on 12/16/21, the laboratory failed to perform calibration on CBC (complete blood count) performed on the Medonic M Series every 6 months as required by the manufacturer. Findings include: 1. Review of the Medonic M Series calibration records revealed calibration was performed on 8 /18/20 and on 3/14/21. No calibration had been performed on the hematology analyzer since 3/14/21. These calibration time frames exceed the 6 month mandatory calibration requirement: 2. Interview with the TC at 12:30 p.m. on 12/16/21 confirmed CBC calibrations were not performed every 6 months as evidenced by the calibration records available. THIS IS A REPEAT DEFICIENCY
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on testing personnel records available on 12/16/2021, the CMS (Centers for Medicare and Medicaid Services) 209 personnel form, and interview with the TC/LD (technical consultant/laboratory director), the LD had not ensured that all testing personnel had received the appropriate training to perform testing with the Boule Medonic M Series hematology analyzer prior to testing patients. There was no documentation that Testing Personnel #2, #3, and #4 as listed on the CMS-209 personnel form had received appropriate training on the Medonic M series. The laboratory overview training was signed by someone other than a qualified TC/LD. Findings Include: 1. Based on laboratory training documentation available the day of survey, it was determined no documented training specific for the Medonic hematology analyzer had taken place before TP #2, #3 and #4 as listed on the CMS 209 form began testing patients. The documented checklist (laboratory training log) had been completed by someone other than the TC or LD. 2. Interview with the TC /LD at 1:30 p.m. on 12/16/21 confirmed that laboratory initial training for TP #2, #3 and #4 was documented as performed by someone other than the TC or LD.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS) database proficiency testing (PT) report, and confirmation by the technical consultant/laboratory director (TC/LD) and laboratory staff at 11:00 a.m. on 12/16/21, the TC failed to ensure the laboratory participated in an HHS approved PT program for CBC (complete blood Count) performed on the Medonic M Series hematology analyzer, for the 3rd event of 2021. Findings include: 1. Interview with the TC/LD and laboratory staff on the day of the survey at 11:00 am confirmed the laboratory did not participate in the 3rd event of 2021 for hematology testing (CBC). 2. Review of the laboratory proficiency records for 2019, 2020 and 2021, and the CMS database Oscar report revealed no proficiency records available for the 3rd event 2021 and no participation. The technical consultant must ensure the laboratory is enrolled and participates in all 3 events in an approved proficiency program for the testing performed by the laboratory.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory testing records from 12/2/19 through the day of survey and interview with the technical consultant/laboratory director (TC/LD) as listed on the CMS-209 form (Centers of Medicare & Medicaid Services) at 1:30 p.m. on 12/16 /21, maintenance and temperature records listed below had not been documented as reviewed by the TC. Findings Include: 1. Review of the laboratory records from December 2019 through 12/16/21 revealed the following records were not documented as reviewed by the TC: a. Boule Medonic M Series hematology maintenance records from 12/2/19 through 12/16/21 b. Temperature records (room, refrigerators, freezers, humidity) from 12/2/19 through 12/16/21 2. Interview with the TC/LD at 1:30 p.m. on 12/16/21 confirmed there was no documented review of these records by the TC during this time period.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel records from 9/12/19 through 12/16/21, the

	Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the technical consultant/laboratory director (TC/LD), the TC failed to evaluate and document the performance of TP #4 at least semiannually during the first year of employment. A semiannual evaluation must be performed during the first year of employment by the technical consultant. Findings include: 1. Review of the personnel records for TP #4 revealed there was no semiannual evaluation/competency documented as performed by the technical consultant during the first year of testing patients. TP #4 began employment on 4/17/21. 2. Interview with the TC/LD at 2:00 p. m. on 12/16/21, confirmed the 6 month evaluation/competency had not been performed on TP #4.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with the technical consultant/laboratory director (TC/LD), the TC failed to evaluate annually and document the performance of TP #1 who is responsible for performing moderate CBC (complete blood count) testing. Findings include: 1. Based on laboratory personnel records available for review on the day of survey, there were no annual evaluations/competencies performed by the technical consultant on TP #1 since the last survey on 9/12/19. The only evaluation available the day of survey for TP #1 was on nursing/office responsibilities and performed by non-lab personnel. 2. Interview with the TC/LD confirmed no annual evaluation/competency for TP #1 had been documented as performed by the TC for the years 2020 and 2021.